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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,061	06/26/2001	Nicholas R. Bachur JR.	P-5026	1747

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EXAMINER	
BEISNER, WILLIAM H	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/892,061	BACHUR ET AL	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 3, 4, 6, 8-10, 20, 22, 24, 26-29, 59 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030).

The reference of Sussman et al. discloses a device and method of use for detection of the presence of biological activity in a sealed container utilizing infrared analysis of a gas (carbon dioxide) in at least one container (13). The device includes an energy emitting device (15) adapted to emit an energy signal toward the container wherein the energy signal has substantially a single wavelength band that is equal to a wavelength band at which the desired gas absorbs the energy signal (See column 6, lines 25-33). The device includes a detector (17) and a signal analyzer (See column 6, lines 59-68, and Figures 5 and 6) to determine the concentration of the gas and/or whether the gas exists in the container. Also, the container of Sussman et al. is capable of optically transmitting the energy signal from the emitting device to the detector.

While the detection and signal analyzer of the reference of Sussman et al. is able to determine whether the monitored gas is exists in the container, instant claims 1 and 20 require that a laser is employed to generate the required energy. Specifically, the reference of Sussman et al. discloses the use of a Nicolet 5-MX FT-IR spectrophotometer for determining the

concentration of carbon dioxide within the container which is indicative of the growth or presence of microorganisms within the container.

The reference of Wrobel et al. first discloses that "Infrared absorption spectroscopy is a classical method for the detection and quantification determination of numerous gases and vapors" (See column 1, lines 10-12). The reference also discloses that some instruments for IR spectroscopy are inadequate due to narrow absorption linewidths of some gases (See column 1, lines 12-16). The reference of Wrobel et al. also discloses that the use of semiconductor diode lasers in the design of infrared spectrometers is advantageous because they are "tunable" over a wide range of wavelengths and because of their relative simplicity, efficiency and small size (See column 1, lines 21-26).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention to employ an infrared absorption spectroscopy device as suggested by the reference of Wrobel et al. in the system of the primary reference of Sussman et al. for the known and expected result of providing an art recognized means for performing classical infrared absorption spectroscopy while providing the benefits associated with the use of a tunable semiconductor diode laser device.

With respect to claims 3 and 22, the reference of Sussman et al. is employing a wavelength band to determine concentration of carbon dioxide within the container (See column 6, lines 25-33).

With respect to claims 4 and 24, the signal analyzer of the primary reference is determining an absorption by the targeted gas.

With respect to claims 6 and 26, the reference is identifying the presence of microorganisms within the container.

With respect to claims 9 and 28, the wavelength bands employed are considered infrared light (emitting device 15).

With respect to claims 10 and 29, the system includes a spectrograph device (See column 6, lines 59-68, and Figures 5 and 6).

3. Claims 2, 7, 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) taken further in view of Fraatz et al.(EP 0448923).

The combination of the references of Sussman et al. and Wrobel et al. has been discussed above.

The above claims differ by reciting that other gas components other than carbon dioxide are detected by the detection system.

The reference of Sussman et al. discloses that while the metabolic product of interest in the examples is carbon dioxide, other metabolically formed gases may be detected (See column 6, lines 25-34).

The reference of Fraatz et al. discloses that it is desirable to detect other gas components other than carbon dioxide when detecting for biological activity within a sealed culture vessel (See page 3, lines 31-24).

In view of these teachings, it would have been obvious to one of ordinary skill in the art to modify the system of the primary reference so as to detect gases other than carbon dioxide

within the vessel by merely providing a wavelength band of light that corresponds to the desired gas to be monitored within the culture vessel. This would be facilitated by the use of the spectrometer system suggested by the reference of Wrobel et al.

4. Claims 39-41 and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) taken further in view of Carr et al.(US 5,888,825).

The combination of the references of Sussman et al. and Wrobel et al. has been discussed above.

While the system of Sussman et al. discloses interrogation of a plurality of sample vessels positioned on a movable carousel relative to a fixed sensing system, the reference does not disclose that the sample containers are positioned in a column/row matrix and/or the that light source and detector are provided within a movable housing that can monitor each of the retained vessels.

The reference of Carr et al. discloses that it is known in the art to position a plurality of sample vessels within a housing (302) and to provide a light source and detector within a movable housing (1024) that can monitor each of the vessels by moving within the matrix of vessels.

In view of this teaching, it would have been obvious to provide the system of the primary reference in a culture apparatus as disclosed by the reference of Carr et al. for the known and expected result of providing a means recognized in the art for providing an incubation

environment for a plurality of sample vessels while allowing non-invasive monitoring of the sample vessels.

5. Claims 51, 52, 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) taken further in view of Berndt et al.(US 5,518,923).

The combination of the references of Sussman et al. and Wrobel et al. has been discussed above.

While the system of Sussman et al. discloses interrogation of a plurality of sample vessels positioned on a movable carousel relative to a fixed sensing system, the reference does not disclose that the sample containers are positioned within a housing with openings.

The reference of Berndt et al. discloses that it is known in the art to employ a housing (30) with a plurality of openings for receiving sample vessels (21). The samples are moved passed a plurality of detection devices (41).

In view of this teaching, it would have been obvious to provide the system of the primary reference in a culture apparatus as disclosed by the reference of Berndt et al. for the known and expected result of providing a means recognized in the art for providing an incubation environment for a plurality of sample vessels while allowing non-invasive monitoring of the sample vessels.

6. Claims 5, 11, 13, 15, 17, 18, 19, 25, 30, 32, 34, 36, 37, 38, 60 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) taken further in view of Waters (US 4,952,498) and Brace (US 5,614,718).

The combination of the references of Sussman et al. and Wrobel et al. has been discussed above.

The above claims differ by reciting that the IR spectrometry provides an indication of pressure within the culture vessel.

The reference of Waters discloses that a change of pressure within a culture vessel is indicative of the presence of a gas-generating microorganism (See the abstract).

The reference of Brace discloses that it is known in the art to correlate the results of the detection of carbon dioxide concentration using IR spectrometry to pressure of carbon dioxide within the sealed vessel (See column 5, lines 8-25).

In view of these references, it would have been obvious to one of ordinary skill in the art to employ the IR spectrometry results of the primary reference as a means to determine the pressure and/or change of pressure within the sealed culture vessel over time as an alternative means recognized in the art for indicating the presence of a gas-generating microorganism within the vessel.

7. Claims 12, 14, 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030), Waters (US 4,952,498) and Brace (US 5,614,718) taken further in view of Fraatz et al.(EP 0448923).

The combination of the references of Sussman et al.; Wrobel et al.; Waters and Brace has been discussed above.

The above claims differ by reciting that other gas components other than carbon dioxide are detected by the detection system.

The reference of Sussman et al. discloses that while the metabolic product of interest in the examples is carbon dioxide, other metabolically formed gases may be detected (See column 6, lines 25-34).

The reference of Fraatz et al. discloses that it is desirable to detect other gas components other than carbon dioxide when detecting for biological activity within a sealed culture vessel (See page 3, lines 31-24).

In view of these teachings, it would have been obvious to one of ordinary skill in the art to modify the system of the primary reference so as to detect gases other than carbon dioxide within the vessel by merely providing a wavelength band of light that corresponds to the desired gas to be monitored within the culture vessel. This would be facilitated by the use of the spectrometer system suggested by the reference of Wrobel et al.

8. Claims 42-44 and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030), Waters (US 4,952,498) and Brace (US 5,614,718) taken further in view of Carr et al.(US 5,888,825).

The combination of the references of Sussman et al.; Wrobel et al.; Waters and Brace has been discussed above.

While the system of Sussman et al. discloses interrogation of a plurality of sample vessels positioned on a movable carousel relative to a fixed sensing system, the reference does not disclose that the sample containers are positioned in a column/row matrix and/or the that light source and detector are provided within a movable housing that can monitor each of the retained vessels.

The reference of Carr et al. discloses that it is known in the art to position a plurality of sample vessels within a housing (302) and to provide a light source and detector within a movable housing (1024) that can monitor each of the vessels by moving within the matrix of vessels.

In view of this teaching, it would have been obvious to provide the system of the primary reference in a culture apparatus as disclosed by the reference of Carr et al. for the known and expected result of providing a means recognized in the art for providing an incubation environment for a plurality of sample vessels while allowing non-invasive monitoring of the sample vessels.

9. Claims 53, 54, 57 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030), Waters (US 4,952,498) and Brace (US 5,614,718) taken further in view of Berndt et al.(US 5,518,923).

The combination of the references of Sussman et al.; Wrobel et al.; Waters and Brace has been discussed above.

While the system of Sussman et al. discloses interrogation of a plurality of sample vessels positioned on a movable carousel relative to a fixed sensing system, the reference does not disclose that the sample containers are positioned within a housing with openings.

The reference of Berndt et al. discloses that it is known in the art to employ a housing (30) with a plurality of openings for receiving sample vessels (21). The samples are moved passed a plurality of detection devices (41).

In view of this teaching, it would have been obvious to provide the system of the primary reference in a culture apparatus as disclosed by the reference of Bemdt et al. for the known and expected result of providing a means recognized in the art for providing an incubation environment for a plurality of sample vessels while allowing non-invasive monitoring of the sample vessels.

Response to Arguments

10. Applicant's arguments in view of the newly recited claim limitations, see pages 12-13, filed 29 March 2004, with respect to the rejection(s)of claim(s) 1, 3-7, 9-11, 13, 15, 18-20, 22-30, 32, 35, 37 and 38 under 35 USC 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030).

11. Applicant's arguments with respect to the combination of the references of Perks et al. with the other references of record have been considered but are moot in view of the new

ground(s) of rejection in view of the combination of the references of Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030).

With respect to Applicants' comments directed to the teachings of the reference of Fraatz et al., the reference of Fraatz et al. has been cited as a teaching reference that suggests other gases that are known in the art to be detected within a sealed culture container. The previously discussed disclosures of Sussman et al. and Wrobel et al. clearly suggest that other gases can be measured using IR spectroscopy.

With respect to Applicants' comments directed to the teachings of the reference of Kruezer et al., the reference of Kruezer et al. has not been applied against the amended claims since the reference of Wrobel et al. now suggests the use of a laser source in IR spectroscopy.

With respect to Applicants' comments directed to the teachings of the reference of Carr et al., the reference of Carr et al. was relied upon as merely as a tertiary reference that suggests that it is conventional in the art to position a light source and detector within a movable housing. The use of a laser to detect the presence of microorganisms within a sealed vessel without a deformable septa has been suggested by the combination of the references of Sussman et al. and Wrobel et al. Note the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

With respect to Applicants' comments directed to the teachings of the reference of Berndt et al., the reference of Berndt et al. was relied upon as merely as a tertiary reference that suggests

that it is conventional in the art to position containers on a turntable for interrogation by a light source and detector. The use of a laser to detect the presence of microorganisms within a sealed vessel without a deformable septa has been suggested by the combination of the references of Sussman et al. and Wrobel et al. Note the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

With respect to Applicants' comments directed to the teachings of the references of Waters and Brace, the reference of Waters was cited merely as a tertiary reference that suggests to one of ordinary skill in the art that the presence of pressure changes within a sealed culture vessel is known in the art to indicate the presence of a microorganism. The reference of Brace is relied upon to establish that one of ordinary skill in the art would recognize that IR spectroscopy can also be used to indicate pressures changes. Additionally, while applicants comment that the instant invention involves the use of width of the absorption peak for detection of pressure, the instant claims are devoid of any language commensurate in scope with these comments. It is noted that claims 1 and 20 merely recite "a signal analyzer chosen to analyze said detected portion of said energy signal to determine whether said gas exists in said container" and claims 11 and 30 merely recited "analyzing said detected portion of said energy signal to determine whether a pressure exists in said container".

For the reasons advance above, Applicants' comments have not be found to be persuasive and the claims of record have not been deemed allowable over the prior art of record.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

William H. Beisner
Primary Examiner
Art Unit 1744

WHB